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TOWNSEND and CONVICEND and CREWTIP

Damela Skelton

Attorney Docket No.: 021819-000120US Client Ref. No. JUV2879.54DIV

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Steven W. Dow, et al.

Application No.: 10/772,913

Filed: February 5, 2004

For: SYSTEMIC IMMUNE

ACTIVATION METHOD USING NUCLEIC ACID-LIPID COMPLEXES

Customer No.: 20350

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Confirmation No.: 5237

Examiner: Anne Marie Sabrina Wehbe

Art Unit: 1633

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

§1.98

Sir:

The references cited on attached forms PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of references BR, BV-BZ and CS-DJ are enclosed. In accordance with 37 CFR §1.98(d), copies of references BO-BQ, BT-BU and CA-CR can be found in Application No. 09/104,759, filed June 25, 1998, now issued U.S. Patent No. 6,693,086 (Attorney Docket No. 021819-000100US).

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It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that <u>no fee is required</u> for submission of this statement, because this submission is prior to the issuance of a first Office Action on the merits.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Karen Babyak Dow

Karen B. Dow Reg. No. 29,684

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KBD:tsp 60913024 v1 NOV 1 4 2006

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

 Complete if Known

 Application Number
 10/772,913

 Filing Date
 February 5, 2004

 First Named Inventor
 Dow, Steve W.

 Art Unit
 1633

 Examiner Name
 Anne Marie Sabrina Wehbe

 Attorney Docket Number
 021819-000120US

(Use as many sheets as necessary)
Sheet 1 of

**U.S. PATENT DOCUMENTS** Pages, Columns, Lines, Where Cite No.1 **Publication Date** Name of Patentee or **Document Number** Relevant Passages or Relevant Figures Appear MM-DD-YYYY Applicant of Cited Document Initiats' Number Kind Code<sup>2 (# known)</sup> 09/18/1990 Huang US-4,957,735 05/07/1991 Woodle, et al. US-5,013,556 ΑB 08/27/1991 Huang, et al. AC US-5.043.164 03/21/1995 Anderson, et al US-5,399,346 AD 12/03/1996 Felgner, et al. ΑE US-5,580,859 US-5,589,466 12/31/1996 Felgner, et al. ΑF 01/41/1997 Weiner, et al. US-5,593,972 AG 06/24/1997 Debs, et al. ΑH US-5,641,662 07/01/1997 Robinson, et al. US-5,643,578 ΑI 09/02/1997 Hutcherson, et al. AJ US-5,663,153 US-5,676,954 10/14/1997 Brigham ΑK 10/21/1997 Carson, et al. US-5,679,647 ΑL Tagawa, et al. US-5,686,101 11/11/1997 AM Wolff, et al. 12/02/1997 ΑN US-5,693,622 12/30/1997 Felgner, et al. AO US-5,703,055 12/30/1997 Johnston et al. ΑP US-5,703,057 US-5,705,187 01/06/1998 Unger AQ Bally, et al. AR US-5,705,385 01/06/1998 Hutcherson, et al. 03/03/1998 US-5,723,335 AS Tirosh, et al. 10/06/1998 ΑT US-5,817,856 US-5,820,873 10/13/1998 Choi, et al. ΑIJ 10/27/1998 Debs, et al. ΑV US-5.827.703 AW US-5,830,878 11/03/1998 Gorman, et al. 11/02/1999 Wheeler, et al. US-5,976,567 ΑХ Wheeler, et al. 11/09/1999 AY US-5,981,501 09/19/2000 Huang, et al. ΑZ US-6,121,247 02/27/2001 Krieg, et al. US-6,194,388 B1 BA 03/27/2001 Krieg, et al. BB US-6,207,646 B1 05/01/2001 Li, et al. BC US-6,224,901 B1 05/29/2001 Krieg, et al. US-6,239,116 B1 BD Semple, et al. 09/11/2001 ΒE US-6,287,591 B1 01/15/2002 Krieg, et al. BF US-6,339,068 B1 06/18/2002 Davis, et al. BG US-6,406,705 B1 03/18/2003 Wheeler, et al. US-6,534,484 B1 BH 07/2003 Raz, et al. ВΙ US-6,589,940

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Examiner	Date	
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For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 

Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 

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60913024 v1

Substitute for form 1449A/PTO				Complete if Known		
				Application Number	10/772,913	
IN	<b>FORMATION DISC</b>	CLO	SURE	Filing Date	February 5, 2004	
S	STATEMENT BY APPLICANT			First Named Inventor	Dow, Steve W.	
				Art Unit	1633	
	(Use as many sheets as ne	ecessar	v)	Examiner Name	Anne Marie Sabrina Wehbe	
Sheet	2	of	6	Attorney Docket Number	021819-000120US	
		PPLI	CANT	First Named Inventor Art Unit Examiner Name	Dow, Steve W. 1633 Anne Marie Sabrina W.	/ehbe

	U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	BJ	US-6,627,615 B1	09/30/2003	Debs, et al.				
***************************************	вк	US-US2002/0110586 A1	08/15/2002	Madden, et al.				
,,	BL	US-US2002/0119990 A1	08/29/2002	Madden, et al.				
	ВМ	US-US2003/0082228 A1	05/01/2003	Flowers, et al.				
	BN	US-						

	FOREIGN PATENT DOCUMENTS										
Examiner	No. <sup>1</sup>				Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages				
Initials*		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	T <sup>6</sup>			
	во	PCT	WO94/04196	A1	03/03/1994	Imperial Cancer Research Technology Limited					
	ВР	РСТ	WO93/25673	A1	12/23/1993	The Regents of the University of California					
·····	BQ	EP	0819758	A2	01/21/1998	James Archibald Mixson					
	BR	РСТ	WO99/66879	A2	12/29/1999	National Jewish Medical Research Center					
	BS										

Examiner	Date	
Signature	Considered	

Substitute	for form 1449B/PT	0		Complete if Known			
				Application Number	10/772,913		
INFO	RMATION	DISCLOS	SURE	Filing Date	February 5, 2004		
STATEMENT BY APPLICANT				First Named Inventor	Dow, Steve W.		
				Art Unit	1633		
	(Use as many she	ets as necessary)		Examiner Name	Anne Marie Sabrina. Wehbe		
Sheet	3	of	6	Attorney Docket Number	021819-000120US		

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-iss and/or country where published.	ropriate), title of the item (book, ue number(s), publisher, city	T 2		
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•••••	BW	GAO, Xiang "Cationic Lipid-Based Gene Delivery: An Update", (un	ndated) pp 99-112			
	вх	RODMAN, David M., et al. "Delivery of Genes Through the Lung C Chapter 9, pp. 181-191	Circulation", (undated)			
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	CA	BALLAS, Zuhair K., et al. "Induction of NK Activity in Murine and H in Oligodeoxynucleotides and Bacterial DNA", <i>Journal of Immunology</i>	luman Cells by CpG Motifs ogy (1996) 157:1840-1845			
	СВ	KRIEG, Arthur M. "Lymphocyte activation by CpG dinucleotide mo <i>Trends in Microbiology</i> (1996) 4(2):73-77	tifs in prokaryotic DNA",			
	СС	PISETSKY, David S. "The Immunologic Properties of DNA", The J (1996) 156:421-423	loumal of Immunology			
	CD	SATO, Yukio, et al. "Immunostimulatory DNA Sequences Necessa Gene Immunization", <i>Science</i> (1996) 273:352-354	ary for Effective Intradermal			
	CE	STACEY, Katryn J., et al. "Macrophages Ingest and Are Activated Journal of Immunology (1996) 157:2116-2122	by Bacterial DNA", The			
Examiner Signature		Date Considered				

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1 Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Substitute	for form 1449B/PT	0		Complete if Known		
				Application Number	10/772,913	
INFO	RMATION	DISCLOS	SURE	Filing Date	February 5, 2004	
STATEMENT BY APPLICANT				First Named Inventor	Dow, Steve W.	
				Art Unit	1633	
	(Use as many she	ets as necessary)		Examiner Name	Anne Marie Sabrina. Wehbe	
Sheet	4	of	6	Attorney Docket Number	021819-000120US	

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ2		
	CF	SUN, Siquan, et al. "Dual Function of Drosophila Cells as APCs for Native CD8 <sup>+</sup> TCells: Implications for Tumor Immunotherapy", <i>Immunity</i> (1996) 4:555-564			
	CG	LIU, Yong, et al. "Factors influencing the efficiency of cationic liposome-mediated intravenous gene delivery", <i>Nature Biotechnology</i> (1997) 15:167-173			
	сн	LEITNER, Wolfgang W., et al. "DNA and RNA-based vaccines: principles, progress and prospects" <i>Vaccine</i> (2000) 18:765-777			
	CI	LESOON-WOOD, Leslie A., et al. "Systemic Gene Therapy with p53 Reduces Growth and Metastases of a Malignant Human Breast Cancer in Nude Mice", <i>Human Gene Therapy</i> (1995) 6:395-405			
	CJ	OKAMOTO, T., et al. <i>Proceedings of the American Association for Cancer Research</i> (1997) 38: Abstract #78			
	ск	LI, Xiu-Min, et al. "Mucosal IFN-λ Gene Transfer Inhibits Pulmonary Allergic Responses in Mice", <i>The Journal of Immunology</i> (1996) 157:3216-3219			
	CL	McLEAN, John W., et al. "Organ-specific endothelial cell uptake of cationic liposome-DNA complexes in mice", <i>American Journal of Physiology</i> (1997) 273:H3878-H404			
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	CN	ROMAN, Mark, et al. "Immunostimulatory DNA sequences function as T helper -1- promoting adjuvants", <i>Nature Medicine</i> (1997) 3(8):849-854			
	со	ROSENBERG, Steven A., et al. "Regression of Established Pulmonary Metastases and Subcutaneous Tumor Mediated by the Systemic Administration of High-docse Recombinant Interleukin 2", <i>J. Exp. Med.</i> (1985) 161:1169-1188			
	СР	SCHEULE, Ronald K., et al. "Basis of Pulmonary Toxicity Associated with Cationic Lipid-Mediated Gene Transfer to the Mammalian Lung", <i>Human Gene Therapy</i> (1997) 8:689-707			
	cq	TEMPLETON, Nancy S., et al. "Improved DNA: liposome complexes for increased systemic delivery and gene expression", <i>Nature Biotechnology</i> (1997) 15:647-652			
Examiner Signature		Date Considered			

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	(Use as many sheets a	s necessary)		Examiner Name	Anne Marie Sabrina. Wehbe	
Sheet	5	of	6	Attorney Docket Number	021819-000120US	

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	CR	GREGORIADIS, Gregory, et al. "Liposome-mediated DNA vaccination", FEBS Letters (1997) 402:107-110				
	cs	NAITOH, J., et al. <i>Proceedings of the American Association for Cancer Research</i> (1998) 39: Abstract #2421				
	СТ	HO, Rodney J.Y., et al. "Interactions of Target-sensitive Immunoliposomes with Herpes Simplex Virus", <i>Journal of Biological Chemistry</i> (1987) 262(29):13979-13984				
	cu	HO, Rodney J.Y., et al. "Target-sensitive Immunoliposomes as an Efficient Drug Carrier for Antiviral Activity", <i>Journal of Biological Chemistry</i> (1987) 262(29):13973-13978				
	cv	HO, Rodney J.Y., et al. "Target-sensitive Immunoliposomes: Preparation and Characterization", <i>Biochemistry</i> (1986) 25:5500-5506				
	cw	ALLEN, T.M., et al. "Large unilamellar liposomes with low uptake into the reticuloendothelial system", FEBS Letters (1987) 223(1):42-46				
	сх	KLIBANOV, Alexander L. "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes", <i>FEBS Letters</i> (1990) 268(1):235-237				
	СҮ	WOODLE, Martin C., et al. "Sterically stabilized liposomes", <i>Biochimica et Biophysica Acta</i> (1992) 1113:171-199				
	cz	CORNELIE, S., et al. "Methylated cpG-Containing Plasmid Activates the Immune System", Scandinavian Journal of Immunology (2004) 59:143-151				
	DA	SASAKI, Shin, et al. "Adjuvant formulations and delivery systems for DNA vaccines", Methods (2003) 31:243-254				
	DB	C.J. WHEELER, et al. "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung", <i>Proc. Natl. Acad. Sci. USA</i> (1996) 93:11454-11459				
	DC	LIU, Y, et al. "Cationic Liposome-mediated intravenous Gene Delivery", J. Biol. Chem. (1995) 270(42):24864-24870				
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	DD	ZOU, Yiyu, et al. "Effective Treatment of Early Endobronchial Cancer With Regional Administration of Liposome-p53 Complexes", <i>J. Natl. Cancer. Inst.</i> (1998) 90(15):1130-1137					
	DE	OUDRHIRI, Noufissa, et al. "Gene transfer by guanidinium-cholesterol cationic lipids into airway epithelial cells <i>in vitro</i> and <i>in vivo</i> ", <i>Proc. Natl. Acad. Sci. USA</i> (1997) 94:1651-1656					
	DF	STRIBLING, Roscoe, et al. "Aerosol gene delivery in vivo", Proc. natl. Acad. Sci. USA (1992) 89:11277-11281					
	DG	NABEL, Gary.J., et al. "Direct gene transfer with DNA-liposome complexes in melanoma: Expression, biologic activity, and lack of toxicity in humans", <i>Proc. Natl. Acad. Sci. USA</i> (1993) 90:11370-11311					
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	DI	PHILIP, Ramila, et al. " <i>In Vivo</i> Gene Delivery", <i>J. Biol. Chem.</i> (1993) 268(22):16087-16090					
	DJ	HIROAKI, Hemmi, et al. Nature Immunology (2002) 3(2): 196-200					
	DK						

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Examiner Signature	Date Considered	

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